REMARKS

In the Office Action dated January 7, 2005, the Examiner has set forth a requirement for restriction under 35 U.S.C. § 121, alleging that the subject matter defined by the claims of the present invention represents the following seven separate and distinct inventions:

Group I. Claims 1-10, drawn to nucleic acids encoding *C. elegans* chloride intracellular channel protein, recombinant vectors comprising said nucleic acids, cells comprising said vectors, and methods of making said protein, classified in class 536, subclass 23.5.

Group II. Claims 11-19, drawn to antibodies that specifically recognize *C. elegans* chloride intracellular channel protein, classified in class 530, subclass 387.9.

Group III. Claims 20-22, drawn to a method of identifying an agent that inhibits CLIC activity, classified in class 435, subclass 7.1.

Group IV. Claims 23-26, drawn to a method of identifying an agent that inhibits CLIC expression or function in wild-type *C. elegans* embryos or cells, classified in class 435, subclass 4.

Group V. Claims 27-30, drawn to a method of identifying an agent that inhibits CLIC expression, classified in class 435, subclass 6.

Group VI. Claims 31-33, drawn to a method of determining if a CLIC gene is involved in tubulogenesis, classified in class 435, subclass 455.

Group VII. Claims 34-39, drawn to a method of identifying an agent that inhibits CLIC expression of function in exc-4 mutant *C. elegans* embryos or cells, classified in class 435, subclass 455.

Additionally, the Examiner applied two species elections. Specifically, if Group III, IV, V or VII is elected, a single disclosed species from a-j must be selected

a. A peptide

b. A nucleic acid

c. An antibody

d. A drug

e. A compound

f. A molecule

g. A dominant-negative antagonist

h. Indanyloxyacetic acid-94

i. N-ethylmalemide

j. glutathione

If Group VI or VII is elected, one human CLIC gene from the six CLIC genes listed in Claims 33 and 36 must be selected.

The Examiner admits that Groups I and each of Groups V, VI, and VII are related as product and process of use but alleges they are distinct inventions because the product as claimed can be used in a materially different process of using that product. The Examiner states that Groups I and both III and IV are unrelated in that they are not disclosed as capable of use together. Specifically, the Examiner alleges that the nucleic acids, vectors, and transformed cells of Group I are not used in the methods of inventions III or IV. The Examiner further alleges that Groups I, III and IV have a separate status in the art as shown by their different classifications, thereby rendering their search burdensome. The Examiner contends that Groups I and II are unrelated because Group II is an antibody molecule, which is chemically distinct from the nucleic acids, vectors, and transformed cells of Group I. The Examiner alleges separate status in the art based on different classification, thereby rendering their search burdensome. The Examiner alleges that Groups II and each of III-VII are unrelated because the invention of Groups II and each of the other groups do not use or rely upon the antibody molecule of Group II. The Examiner alleges separate status in the art based on different classification, thereby rendering their search burdensome. The Examiner alleges that Groups III, IV, V, VI and VII are unrelated to each other because Group III is an assay which is narrowly focused on the activity of a single type of chloride channel whereas Group V measures *exc-4* gene expression; Group VI is an assay for phenotype rescue of mutant *C. elegans* by recombinant gene expression; Group VII encompasses phenotypic rescue of mutant *C. elegans* as well as screening of agents for a broad scope of effects that includes effects on excretory cell phenotype, CLIC gene expression and direct effects on

CLIC protein. Again, the Examiner alleges separate status in the art based on different classification, thereby rendering their search burdensome.

In order to be fully responsive to the Examiner's requirements for restriction, Applicant provisionally elects to prosecute the subject matter of Group I, Claims 1-10, drawn to nucleic acids encoding *C. elegans* chloride intracellular channel protein, recombinant vectors comprising said nucleic acids, cells comprising said vectors, and methods of making said protein. However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicant hereby traverses the Examiner's requirement for restriction and species election and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added).

The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions, which are both independent *and* distinct, 37 C.F.R. §§ 1.141-142 and a serious burden exists on the examiner in examining the groups of claims. Without a showing of independence and distinctness and a serious burden, a restriction requirement is unauthorized.

More specifically, Applicant respectfully submits that Groups I and each of Groups V, VI, and VII are related as a product and process of use, as the Examiner has conceded. Further, the Examiner has merely stated that Groups I, II, III and IV are unrelated with no explanation as to why the nucleic acids, vectors, and transformed cells of Group I are not used in the methods of Groups III or IV; how the antibody of Group II is chemically distinct from the nucleic acids, vectors, and transformed cells of Group I; how the methods of Groups III-VII do not use or rely on the antibody of Group II; and how Groups III-VII have different modes of operation, different functions, different effects. Thus, in the present application, Groups I-VII are clearly related to each other and are *not* independent. Additionally, the Examiner has not shown that a serious burden exists in examining the groups of claims, as five of the seven groups are in the same class, i.e. 435.

Applicants further submit that the interdependence of Groups I-VII is confirmed-indeed, it is mandated—by virtue of the fact that 35 U.S.C. §112 compels disclosure of all aspects of the invention in the one application which applicants have filed. For example, an application claiming a method of screening for agents inhibiting chloride intracellular channels is required to disclose *inter alia* not only the isolation and characterization of the gene *exc-4* of *C. elegans* but also that the gene encodes an orthologue to the human CLIC family of chloride intracellular channel proteins; the first animal model of this family of ion channel proteins, and antibody directed to *exc-4* protein as well as methods of using to identify putative agents that inhibit CLIC activity or expression. In other words, a description of the means and methods of producing the subject *C. elegans* chloride intracellular channel protein, recombinant vectors comprising said nucleic acids, cells comprising said vectors, an animal model representing the *in vivo* function of the CLIC family of chloride intracellular channel proteins and a genetically tractable screen to identify putative agents that inhibit CLIC expression, function or activity are a mandatory part of the application to methods of screening for agents inhibiting the CLIC family of chloride intracellular channels. Indeed, if any of these aspects of a complete disclosure were omitted, the application could be considered defective under §112, first paragraph. Consequently, it is clear that aspects of a given invention, such as a product and the process of using that process, are necessarily interdependent, not independent, from each other.

The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as Applicant has done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

Applicant respectfully suggests that, in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which

arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications, which are, filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. § 121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, *Studiengesellschaft Kohle GmbH v. Northern Petrochemical Co.*, 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). *In Gerber Garment Technology Inc. v. Lectra Systems Inc.*, 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that § 121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicant respectfully urges the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicant respectfully submits that a determination to make the pending restriction requirement final must evidence the patentable distinctness and a serious burden in examination of all defined seven groups, as presented by the Examiner.

The Examiner has justified the restriction requirement in this case by reference to the different classes of the Patent & Trademark Office classification system in which the seven groups of claims would allegedly be classified. This basis fails to justify the restriction requirement in this application.

Here, Groups III, IV, V, VI and VII are directed to the same class and Groups VI and VII are not only directed to the same class, but the same subclass. This does not support the Examiner's allegation that the inventions are distinct because they have acquired a separate status in the art as shown by their different classification. Therefore, the Examiner has not shown a serious burden exists in examining all seven groups.

Moreover, the classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the subclass(es) with which the Examiner associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patent assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. § 121, which fact proves that basing restriction requirements on the classification system is improper.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Based upon the foregoing, the claims of Groups I-VII all generally relate to an isolated nucleic acid encoding the *exc-4* excretory canal gene of *C. elegans*; an animal model representing the *in vivo* function of the CLIC family of chloride intracellular channel proteins; and a high throughput, genetically tractable screen to identify putative agents that inhibit CLIC expression function or activity. Therefore, Applicant submits that Groups I-VII (claims 1 to 39) should be examined together as one application, as the fields of search involved in examining these groups would, as a practical matter, be essentially co-extensive, and the best interests of the public would be served by having all of the subject matter claimed in these groups in the same application. Accordingly, reconsideration and withdrawal of the restriction requirement is respectfully requested.

No fee is deemed necessary in connection with the filing of this response. Should any fee be required, the Commissioner is hereby authorized to charge payment of any fees associated with the subject application or credit any overpayment to Deposit Account No. 02-4270.

Respectfully submitted,

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